

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Comparing prophylactic effects of polyurethane-Cylindric and Tapered cuffed and Polyvinyl chloride cuffed endotracheal tubes in Prevention of ventilator-associated pneumonia on intubated patients in ICU

Protocol summary

Summary

Objectives)To compare prophylactic effects of polyurethane-Cylindric and Tapered cuffed and Polyvinyl chloride cuffed endotracheal tubes on preventing ventilator-associated pneumonia in intubated patients admitted in ICU. Design) A prospective randomized clinical trial. Participants and settings) Ninety six internal or surgical patients with age range of 18-65 years that have intubated in ICU for first time will randomly allocated in three groups. Patients with intubation before admission in ICU, prior history of immune compromised conditions or pneumonia will exclude from study. Intervention) Intubation will be by polyurethane-Cylindric cuffed endotracheal tubes in group A, polyurethane tapered cuffed in group B and Polyvinyl chloride cuffed in group C. Outcome) All patients will follow for development of ventilator associated pneumonia (VAP).

General information

Acronym

VAP

IRCT registration information

IRCT registration number: **IRCT201112163915N4**

Registration date: **2011-12-21, 1390/09/30**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-12-21, 1390/09/30

Registrant information

Name

Manizheh Mostafa Gharehbaghi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1526 2253

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peirovifara@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Tabriz University of Medical Sciences

Expected recruitment start date

2011-06-22, 1390/04/01

Expected recruitment end date

2012-03-20, 1391/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing prophylactic effects of polyurethane-Cylindric and Tapered cuffed and Polyvinyl chloride cuffed endotracheal tubes in Prevention of ventilator-associated pneumonia on intubated patients in ICU

Public title

Comparing prophylactic effects of polyurethane-Cylindric and Tapered cuffed and Polyvinyl chloride cuffed endotracheal tubes in Prevention of ventilator-associated pneumonia on intubated patients in ICU

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: intubation in ICU for first time; age range 18-65 years; internal medicine or surgical cases.

exclusion criteria: intubation prior to ICU admission;
history of immune compromised conditions; pneumonia.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Gholghasht Street

City

Tabriz

Postal code

Approval date

2011-08-07, 1390/05/16

Ethics committee reference number

5/4/3862

Health conditions studied

1

Description of health condition studied

Ventilator Associated Pneumonia

ICD-10 code

J95.8

ICD-10 code description

Other postprocedural respiratory disorders

Primary outcomes

1

Description

Ventilator associated pneumonia

Timepoint

During hospitalization in ICU

Method of measurement

Chest x-ray (progressive infiltration and consolidation) with two items of body temperature below 36.5 or above 38.5, leukocyte count less than 1500 or more than 10000, purulent tracheal aspirate, positive culture aspirate

Secondary outcomes

empty

Intervention groups

1

Description

group A : intubation with polyurethane-Cylindric cuffed endotracheal tubes,

Category

Treatment - Devices

2

Description

group B: Intubation with polyurethane-Tapered cuffed endotracheal tubes,

Category

Treatment - Devices

3

Description

group C: intubation with Polyvinyl chloride cuffed endotracheal tubes

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada Hospital

Full name of responsible person

Ali Peirovifar

Street address

Operation room, Emam Reza Hospital, Gholghasht street

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Tabriz University of Medical Sciences

Full name of responsible person

Dr Rashidi

Street address

Tabriz university of Medical Sciences, Ghoghhasht Street

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for Research, Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Ali Peirovifar

Position

Associate Professor of Anesthesiology

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty